Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1995

RAYMOND ROSEN,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Whether the Circuit Court properly applied *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L.Ed.2d 469, 113 S.Ct. 2786 (1993) in holding that expert opinion testimony that petitioner's use of a transdermal nicotine patch proximately caused his heart attack was not scientifically reliable and admissible under Rule 702 of the Federal Rules of Evidence (hereinafter "FRE").

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PETITION FOR WRIT OF CERTIORARI

Petitioner, Raymond Rosen, respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Seventh Circuit.

OPINION BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit in *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996) has since been published and is included in an appendix hereto.

JURISDICTION

The opinion and judgment of the United States Court of Appeals for the Seventh Circuit was rendered on March 11, 1996. No petition for rehearing was filed. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

FEDERAL RULES OF EVIDENCE

Rule 402 of the FRE provides:

> All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by act of Congress, by these rules, or by other rules prescribed by the Supreme

Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 702 of the FRE provides:

If scientific, technical, or other specialized knowledge will assist the trier-of-fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

STATEMENT OF THE CASE

In a diversity action brought by petitioner, Raymond Rosen, a cigarette smoker, against Ciba-Geigy Corporation, the manufacturer of a transdermal nicotine patch, the district court granted summary judgment, holding that petitioner had failed to show that the patch was a "substantial factor" in bringing about his heart attack. *Rosen v. Ciba-Geigy Corp.*, 892 F. Supp. 208 (1995).

Petitioner, prior to his heart attack in June 1992, had well preserved left ventricular contractility and overall heart function which favorably placed him in the upper 10% to 15% of the population at his age, regardless of bypass surgery (R.23). Petitioner obtained his patches with a prescription from his doctor 116 days following an order from the Food and Drug Administration that required all manufacturers to include instructions that clearly stated – If you have any cardiovascular conditions, you should discuss alternative ways to stop smoking with your doctor (R.22, R.31). This order was issued

on February 13, 1992 with a 60-day requirement for compliance (R.31). Enclosed with petitioner's patches was a single instruction sheet that did not include the FDA-required warning but only the following under the title "What to Watch for (Adverse Effects)":

> You should not smoke while using the Habitrol patch. It is possible to get too much nicotine (an overdose), especially if you use a Habitrol patch and smoke at the same time. Signs of an over dose would include bad headaches, dizziness, upset stomach, drooling, vomiting, diarrhea, cold sweat, blurred vision, difficulty with hearing, mental confusion and weakness. An overdose might cause you to faint.

(R.22). Contrary to the Circuit Court's opinion, petitioner's doctor testified that the manufacturer provided no warning of adverse cardiac responses as a result of using the patch while smoking (R.22). The Circuit Court did not note that the presence of soap on petitioner's skin while he was bathing after he had smoked two cigarettes had accelerated the delivery of nicotine into his blood system before he sustained his heart attack on June 11, 1992 (R.31).

The Seventh Circuit affirmed summary judgment, holding that petitioner's expert's deposition testimony that the nicotine patch had caused the heart attack was not valid scientific evidence and inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The Court disagreed with the district court which had held that petitioner could not prove causation because the expert had said that his probability of sustaining a heart attack,

regardless of whether he was wearing a nicotine patch, was 95%. Although the Court held that the loss of even a small chance of averting a heart attack was compensable under applicable Illinois tort law, it concluded that the expert's testimony was not scientifically valid. The Court stated:

> Nowhere in [the] deposition is there an explanation of how a nicotine overdose (remember that Rosen was smoking at the time that he was wearing the patch) can precipitate a heart attack, or a reference to a medical or other scientific literature in which such an effect of nicotine is identified and tested. Since [petitioner's expert] is a distinguished cardiologist, his conjecture that nicotine can have this effect and may well have had it on Rosen is worthy of careful attention, even though he has not himself done research of effects of nicotine. But the courtroom is not the place for scientific guess work, even of the inspired sort. Law lags science; it does not lead it.

78 F.3d at 319. No petition for rehearing was filed.

REASONS FOR GRANTING THE WRIT

THE SEVENTH CIRCUIT FAILED TO FOLLOW *DAUBERT V. MERRELL DOW PHARMACEUTICALS, INC.*, BY HOLDING THAT THE RELEVANT OPINION TESTIMONY OF PETITIONER'S QUALIFIED EXPERT WAS NOT SCIENTIFICALLY VALID OR ADMISSIBLE UNDER RULES 402 AND 702 OF THE FEDERAL RULES OF EVIDENCE.

The issue on appeal is a timely one that requires this Court to exercise its supervisory authority over the lower federal courts.

This appeal is from a judgment entered in a products liability action involving a nicotine transdermal patch that may soon be sold to millions of cigarette smokers over the counter. The Circuit Court upheld as inadmissible petitioner's expert's opinions that the patch was a factor in causing his heart attack, although the expert was qualified and his opinions were relevant. If permitted to stand, the decision will allow judges to usurp the jury's factfinding function by vesting them with the unfettered discretion to suppress the truth and directly conflicts with this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

In *Daubert*, this Court expressly repudiated *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), holding that the *Frye* "general acceptance" test was superseded by adoption of the Federal Rules of Evidence. In its stead, this Court outlined a "flexible" inquiry driven primarily by Federal Rules of Evidence 401, 402, 403, and 702. After discussing the "liberal thrust" of the federal rules, as

reflected in Rules 401 and 402, this Court noted that nothing in Rule 702, which governs the admissibility of expert testimony, makes "general acceptance" an absolute prerequisite to admissibility. What that rule did require, this Court held, is that the proffered evidence possesses sufficient evidentiary reliability to be admissible as "scientific, technical, or other specialized knowledge" and that the proffered evidence is relevant in the sense that it will assist the trier-of-fact to understand the evidence or to determine a fact in issue.

Whether evidence assists the trier-of-fact is essentially a relevance inquiry. Under Rule 702, the evidence must possess validity when applied to the pertinent factual inquiry. Validity can be measured by several factors, including whether the theory or technique can be tested. No list of factors is meant to be exhaustive as some of the factors may not be readily applicable in all cases. Certainty is not required in any case.

This Court did not require a scientific opinion to be beyond disproof before it becomes admissible. Rather, this Court admonished lower courts to continue to rely on "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" as the means for dealing with "shaky but admissible evidence."

The Circuit Court, in applying *Daubert*, did not and could not dispute either that Dr. Fozzard, a cardiologist and department head at the University of Chicago, was qualified or that his opinions were relevant. It concluded, however, that his opinions were speculative. The focus of

Daubert is simply whether the expert's opinions are predicated upon scientific knowledge that will assist the trier-of-fact. A judge decides whether the expert is reliable; it is for the jury to decide whether the expert is correct. *See, In Re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3rd Cir. 1994), *cert. denied sub nom. General Electric Co. v. Ingram*, ___ U.S. ___, 115 S.Ct. 1253, 131 L.Ed.2d 134 (1995).

Dr. Fozzard's opinions can certainly be scientifically tested and proven false. If there is any one basic characteristic that marks an assertion as "scientific" from one that is not, it is that the assertion must be capable of being proven false. *See, Sierra Club v. Marita*, 46 F.3d 606, 622 (7th Cir. 1995). Dr. Fozzard's opinions could be proven incorrect by evidence, for example, from other experts retained by the defendant for trial. On this record, however, there was no evidence tending to disprove Dr. Fozzard's opinions. The Circuit Court was less concerned with whether Dr. Fozzard's opinions were capable of being scientifically tested than it was with whether or not they were correct.

Rather than allow the trier-of-fact to decide whether Dr. Fozzard's opinions were correct, the Circuit Court dilated on such other factors that may play a causal role in a heart attack as fatty diet, high blood pressure, or diabetes. The Court analogized nicotine to eggs, shoveling snow, the distress of quitting smoking "cold turkey," or exercise. Among the more curious digressions, the Court speculated that quitting smoking by reducing stress was more likely to precipitate a heart attack than smoking one more cigarette. 78 F.3d at 319. The Circuit Court overstepped its "gatekeeping" responsibilities by

offering disputations of Dr. Fozzard's opinions that were themselves utterly unscientific. Whether Dr. Fozzard's opinions were correct was not the issue for either the district court or the Circuit Court, but for the trier-of-fact alone to decide.

Dr. Fozzard's opinions were based upon scientific studies and relevant evidence. They were capable of being disproved, but the Court relieved the defendant of any need to do so at trial. They were consistent with other evidence available and the circumstances leading up to the heart attack. The product literature recognizes the dangers nicotine pose to patients with coronary histories. The presence of soap on petitioner's skin while bathing speeded the delivery of nicotine in the blood, and petitioner's prescribing doctor testified that a high level of nicotine could have caused a spasm or constriction of a blood vessel that was already blocked resulting in the heart attack (R.22). Vigorous cross-examination, contrary evidence and jury instructions on the burden of proof are the means that the lower courts should have employed. If "law lags science," it should not have been employed as it was by the lower courts as a barrier to the search for truth.

CONCLUSION

For the foregoing reasons, petitioner, Raymond Rosen, prays that a writ of certiorari issue to review the opinion and judgment of the Court of Appeals for the Seventh Circuit.

Respectfully submitted,

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APPENDIX A

App. 1

Raymond ROSEN, Plaintiff-Appellant,

v.

CIBA-GEIGY CORPORATION,
Defendant-Appellee.

No. 95-3064.

United States Court of Appeals,
Seventh Circuit.
Argued Feb. 16, 1996.

Decided March 11, 1996.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division, No. 94 C 4039; James H. Alesia, Judge.

Michael Resis (argued), Paul Sarauskas, Querrey & Harrow, Chicago, IL, for plaintiff-appellant.

Anne G. Kimball (argued), Kevin B. Reid, Elizabeth A. Sanders, Wildman, Harrold, Allen & Dixon, Chicago, IL, for defendant-appellee.

Before POSNER, Chief Judge, and CUMMINGS and BAUER, Circuit Judges.

POSNER, Chief Judge.

The defendant, Ciba-Geigy, manufactures a nicotine patch called "Habitrol." The patch is affixed to the user's skin and delivers nicotine through the skin and into the bloodstream. The goal is to help the user break his cigarette habit by alleviating his craving for nicotine. The patch is available only by prescription. The instructions that accompany the patch warn both the physician and

the patient that the patient should not smoke while wearing the patch and that a patient who has coronary artery disease should be carefully screened before the patch is prescribed for him. The plaintiff, Rosen, a heavy smoker all his adult life, had his first heart attack in 1987, followed by quadruple bypass surgery. He was told to stop smoking, but did not. He experienced chest pains and other cardiac symptoms in the following years, indicating a progression of his coronary artery disease. His previous heart attack, high blood pressure, cholesterol count, age (60 in 1992), and continued smoking placed him at high risk of having another heart attack.

In June of 1992 the cardiologist who was treating Rosen, Dr. Car, prescribed the Habitrol patch and told him not to smoke while wearing it. Rosen affixed the patch to his arm but continued smoking, as, we are told, 75 percent of patch wearers do. Upon awakening on the morning of the third day of wearing the patch, Rosen smoked two cigarettes and then took a bath. During the bath he removed the patch and immediately felt a numbing sensation in the same arm. Later that morning he experienced discomfort in his chest, went to the hospital, and was diagnosed as having had another heart attack. He later resumed smoking and has since had two more heart attacks.

This diversity suit claims that Ciba-Geigy was negligent in developing, marketing, and selling the Habitrol patch. What exactly the negligence is believed to consist in is unclear. It is also unclear why the plaintiff has pleaded negligence rather than, as is usual in a products case, strict liability – though in a case, such as this, involving an alleged defect in the conception or design

rather than manufacture of a product, there may be no difference. *Bammerlin v. Navistar Int'l Transportation Corp.*, 30 F.3d 898, 902 (7th Cir.1994); *Flaminio v. Honda Motor Co., Ltd.*, 733 F.2d 463, 467 (7th Cir.1984). The suit was dismissed on summary judgment for want of an adequate showing of a causal connection between the patch and the heart attack, so the issue of the defendant's alleged breach of its duty of care was not explored. The plaintiff seems to believe either that the warnings of possible harm to people with coronary artery disease are inadequate or that the product is unreasonably dangerous, perhaps because the product is sold to addicts who can be expected to disregard any warnings. For purposes of this appeal we accept these beliefs, without of course vouching for their validity.

When an unusual event follows closely on the heels of another unusual event, the ordinary person infers a causal relation; so it was natural for Mr. Rosen to assume that the heart attack he experienced in June of 1992 was caused either by wearing or removing the patch. The inference is reinforced by the fact that nicotine is a principal ingredient of cigarette smoke, which is known to be a cause of coronary artery disease, and by the fact that the manufacturer of the patch had warned that it might have bad effects on persons who already have the disease. But lay speculations on medical causality, however plausible, are a perilous basis for inferring causality; and though Rosen refers to newspaper accounts of "an epidemic of heart attacks to patch users who smoked" while wearing the patch, we do not understand him to be quarreling with the proposition that without scientific evidence of a causal relation between the nicotine patch and his heart

attack, as distinct from journalistic reports, he cannot prevail in this suit.

Rosen relied for his scientific evidence on the deposition of Dr. Harry Fozzard, a distinguished cardiologist and department head at the University of Chicago. Despite Fozzard's sterling credentials, the district judge ruled that his opinion concerning the role of the nicotine patch in Rosen's heart attack would not be admissible in evidence; and without that evidence Rosen's case was doomed. The judge also thought that Rosen could not prove causality because Fozzard said that the probability that Rosen would have had a heart attack anyway, nicotine patch or no, was 95 percent. But Fozzard did not say when that almost inevitable heart attack would occur; and the loss of even a small chance of averting a serious harm may be compensable under Illinois law (here applicable), as we noted recently in *Murrey v. United States*, 73 F.3d 1448, 1453-54 (7th Cir.1996); see also *Doll v. Brown*, 75 F.3d 1200, 1205-06 (7th Cir.1996).

So the district judge's decision can be sustained only if his ruling on the admissibility of Fozzard's evidence is upheld. Under the regime of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist. As Judge Kozinski has emphasized in his opinion on remand from the Supreme Court's decision in *Daubert*, it is a daunting task for judges who do not have a scientific background (and most do not) to decide whether a scientist's testimony is real science or not. 43 F.3d 1311, 1315-16 (9th Cir.1995).

But they must do the best they can, and we think the district judge was right (and certainly acting within the scope of his discretion) in concluding that Dr. Fozzard's testimony was not real science.

To reach this conclusion we do not have to become philosophers of science and set forth the necessary and sufficient conditions of "real" science. When the Supreme Court in *Daubert* told judges to distinguish between real and courtroom science, it was not with the object of discovering the essence of "science," if there is such an essence. The object, we think, while conceding the uncertainty concerning the reach of the majority opinion discussed in the Chief Justice's separate opinion, 509 U.S. at ___, 113 S.Ct. at 2799, was to make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work. Cf. 509 U.S. at ___-___, 113 S.Ct. at 2796-97; *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106-07 (7th Cir.1994). If they do, their evidence (provided of course that it is relevant to some issue in the case) is admissible even if the particular methods they have used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community. If they do not, their evidence is inadmissible no matter how imposing their credentials. Regarding the second half of this test, the half involved in this case, we said before (but consistently with) *Daubert* that "an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process. . . . Professor Bryan would not accept from his students or those who submit papers to his journal an essay containing neither facts nor reasons; why should a court rely on the sort of exposition the scholar would not

tolerate in his professional life?" *Mid-State Fertilizer Co. v. Exchange National Bank*, 877 F.2d 1333, 1339 (7th Cir.1989).

Dr. Fozzard's deposition, while expressing what may be an insightful, even an inspired, hunch concerning the cause of the heart attack that Rosen experienced in June of 1992, lacks scientific rigor. The deposition offers neither a theoretical reason to believe that wearing a nicotine patch for three days, or removing it after three days, could precipitate a heart attack, or any experimental, statistical, or other scientific data from which such a causal relation might be inferred or which might be used to test a hypothesis founded on theory. The usual kind of heart attack, and the kind that Rosen has now had several times, is a myocardial infarction, which is a sudden, drastic reduction in the flow of blood to the heart as a result of plaque breaking loose from the walls of a coronary artery and forming a clot that blocks the artery. That smoking cigarettes can contribute to the formation of plaque and so play a causal role in heart attacks is now very generally accepted. Whether nicotine, which is only one ingredient of cigarette smoke, can have that effect is much less clear, despite Ciba-Geigy's warnings, which could, though required by the Food and Drug Administration, be overcautious. But let us assume that nicotine can contribute to the formation of plaque. Fozzard mentioned a study of dogs which found this; and though an automatic extrapolation from dogs to human beings would not be warranted, animal studies play an important role in human medical research. Missing from Fozzard's deposition, however, is any recognition of the distinction between the short-run and long-run effects of smoking, fatty diet, high blood pressure, diabetes, and

the other well-known causal factors in coronary artery disease and hence in heart attacks. Wearing a nicotine patch for three days, like smoking for three days, is not going to have a significant longrun effect on coronary artery disease; that much is clear. In the long, gradual progression of Rosen's coronary artery disease those three days were a blink of the eye. The patch could have had no significance for Rosen's health, therefore, unless it precipitated his heart attack in June of 1992. That is an entirely different question from whether nicotine, or cigarettes, are bad for one's arteries.

We are baffled by Fozzard's failure to make this elementary distinction. Shoveling snow can precipitate a heart attack, but it cannot cause coronary artery disease. Eating an omelette every day can (in combination with a genetic or other abnormality that prevents the body from properly regulating the level of cholesterol in the blood) cause coronary artery disease; but eating an omelette three days in a row is exceedingly unlikely to precipitate a heart attack. Quitting smoking is, by inducing stress, more likely to precipitate a heart attack than smoking one more cigarette is likely to do. In this example an event has opposite short-run and long-run consequences for heart attacks – increasing the short-run likelihood and reducing the long-run likelihood. Exercise is a similar example. Nowhere in Fozzard's deposition is there an explanation of how a nicotine overdose (for remember that Rosen was smoking at the same time that he was wearing the patch) can precipitate a heart attack, or a reference to a medical or other scientific literature in which such an effect of nicotine is identified and tested.

Since Fozzard is a distinguished cardiologist, his conjecture that nicotine can have this effect and may well have had it on Rosen is worthy of careful attention, even though he has not himself done research on the effects of nicotine. But the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it. There may be evidence to back up Fozzard's claim, but none was presented to the district court.

Dr. Car's deposition hints that a nicotine overdose might cause an arterial spasm that might in turn cause an infarct. But again no backing from scientific theory or data was offered. There is also no evidence concerning the level of nicotine in Rosen's blood when he had the infarct and Car's own conclusion was that the patch had not caused Rosen's heart attack – a conclusion that Rosen does not like, so he calls Car's deposition "waffling" and says that in it Car "several times made contradictory statements." The district court was within its discretion in concluding that the scientific evidence of causation that the plaintiff offered was not admissible, and therefore in dismissing the suit.

The plaintiff also argues that the district judge taxed "exorbitant" costs, in particular $1,400 for copies, which the plaintiffs calls "outrageous." The plaintiff has made no effort to substantiate these accusations, and we reject them.

AFFIRMED.